Pursuant to ch. 227, Wis. Stats., the Wisconsin Department of Natural Resources has finalized and hereby certifies the following guidance document.

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<td>DOCUMENT TITLE</td>
<td>Evaluating and Managing Pharmaceutical Waste</td>
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DNR CERTIFICATION

I have reviewed this guidance document or proposed guidance document and I certify that it complies with sections 227.10 and 227.11 of the Wisconsin Statutes. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is not explicitly required or explicitly permitted by a statute or a rule that has been lawfully promulgated. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is more restrictive than a standard, requirement, or threshold contained in the Wisconsin Statutes.

[Signature]

November 6, 2019

Date
Introduction

Pharmaceuticals that can no longer be used must be managed as waste. You must evaluate each drug generated at your facility to determine whether it is a solid waste, hazardous waste, infectious waste and/or radioactive waste and then dispose of or otherwise manage it accordingly. All pharmaceutical waste evaluations must be documented and available for inspection.

This fact sheet offers guidance to help healthcare providers properly evaluate and manage pharmaceutical wastes that are generated at their facilities.

What are the environmental and health concerns?

If managed improperly, pharmaceutical waste may harm human health and the environment. Flushing excess pharmaceuticals down the drain has been a common practice for many years. Recent studies indicate, however, that some of these pharmaceuticals may be passing through wastewater treatment systems and entering waterways that serve as drinking water supplies for local municipalities.

To minimize the harmful effects to human health and the environment, the Wisconsin Department of Natural Resources (DNR) recommends that even nonhazardous pharmaceuticals, including most hormones, antibiotics and antidepressants, be disposed of by hazardous waste or solid waste incineration.

What is “pharmaceutical waste”?

Pharmaceutical waste may include, but is not limited to:

- expired drugs;
- patients’ discarded personal medications;
- waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.);
- waste materials containing chemotherapy drug residues;
- open containers of drugs that cannot be used;
- containers that held acute hazardous waste (P-listed) drugs;
- drugs that are discarded; and
- contaminated garments, absorbents and spill cleanup material.

Do I need to evaluate all discarded pharmaceutical materials?

All discarded pharmaceutical materials must be evaluated with two exceptions.

Reverse distribution

Some pharmaceuticals may be returned to the manufacturer or a reverse distributor. Because of their potential for use or eligibility for credit, these pharmaceuticals are not considered waste and therefore do not need to be evaluated. Pharmaceuticals managed this way must not be leaking; partially used liquids or pastes; or display any other characteristics that would reasonably make them ineligible for return. Do not mix returnable pharmaceuticals together or with other non-returnable pharmaceuticals.

“Empty” containers

Pharmaceutical containers that meet the legal definition of “empty” do not need to be evaluated. An “empty” container is defined in s. NR 661.07, Wis. Adm. Code, as meeting all of the following criteria:

- all material that can be removed by normal means has been removed; and
- less than 3 percent by weight of the total container capacity remains; and
- it does not contain residue from a P-listed acute hazardous waste (go to dnr.wi.gov and search “hazardous waste” for assistance in waste determinations).

For more information on empty containers, see https://dnr.wi.gov/files/pdf/pubs/wa/wa1256.pdf. Containers that meet the definition of “empty” may be disposed of as infectious, trace chemotherapy or solid waste, whichever is appropriate.
How should pharmaceutical wastes be managed?

The DNR recommends that all pharmaceutical wastes, including antineoplastic and cytotoxic drugs, be either:
- **incinerated** in a unit licensed or otherwise approved for the destruction of pharmaceutical waste; or
- **returned** to the manufacturer through a reverse distribution program.

Even pharmaceuticals that are not hazardous waste can be endocrine disruptors, carcinogens or mutagens and cause harm to human health and the environment if improperly disposed.

Use the following guidelines for managing pharmaceutical waste:
- Do not mix nonhazardous pharmaceutical waste with infectious waste. Disinfecting infectious waste does not destroy the properties of the drugs.
- Do not flush it to the septic system.
- The DNR strongly discourages the disposal of pharmaceutical waste in a solid waste landfill or sanitary sewer. Disposing of pharmaceuticals by flushing them down the sewer or throwing them into a landfill may result in the drugs showing up in measurable amounts in surface water or groundwater that some communities use for drinking water. The practice of squirting or pouring pharmaceuticals into a sanitary sewer or absorbent material, commonly referred to as “wasting,” is a form of disposal and is not recommended.

Pharmaceutical containers

Manage containers that held P-listed acute hazardous waste, such as inner wrappers for nicotine patches and acute hazardous chemotherapy drugs, as hazardous waste. If properly rinsed three times, containers that held P-listed wastes are considered “empty” and do not require management as hazardous waste. The rinsate, however, is a P-listed acute hazardous waste.

Since drug “containers” often contain sharps, tubing, bags or other materials that pose a risk to the handler and are difficult to rinse, rinsing is not recommended; rather, the entire container plus any contents or residue should be managed as a hazardous waste.

Evaluation tool

Use the attached flow chart to determine whether a pharmaceutical waste is hazardous. Before you begin, make a list of all pharmaceutical wastes generated in your facility. The evaluation should be made at the point of generation prior to any mingling or combining with other wastes.

What other rules apply?

Sometimes pharmaceutical wastes are regulated by both hazardous waste rules and other rules. When evaluating a waste, be sure to consider all regulations that affect how you must manage and dispose of the waste.

For example:
- Pharmaceutical hazardous waste, such as a vaccine containing mercury preservative, may also be regulated as infectious waste. For more information about infectious waste, visit [dnr.wi.gov](http://dnr.wi.gov) search “healthcare waste.”
- Pharmaceutical hazardous wastes, such as waste barbiturates, may also be regulated by the U.S. Drug Enforcement Administration (DEA) as controlled substances. For more information, see [www.dea.gov](http://www.dea.gov).
- Pharmaceutical hazardous wastes, such as a waste liquid scintillation cocktail, may also be regulated by the U.S. Nuclear Regulatory Commission as a radioactive waste. See [https://www.nrc.gov/waste/low-level-waste.html](https://www.nrc.gov/waste/low-level-waste.html) and [https://www.dhs.wisconsin.gov/radiation/radioactive-materials/index.htm](https://www.dhs.wisconsin.gov/radiation/radioactive-materials/index.htm) for more information about NRC radioactive waste requirements.
- Pharmaceutical waste discharged to the sanitary sewer is subject to DNR’s wastewater regulations. Local sewerage authorities may also have a Sewer Use Ordinance with their own discharge requirements. Contact your local sewerage authority if you have questions about discharges to the sanitary sewer or see ch. NR 211, Wis. Adm. Code.

Where can I get more information?

Waste management

DNR waste management specialists are available to help you with your questions regarding the management of solid waste, hazardous waste, infectious waste and medical waste. Go to [dnr.wi.gov](http://dnr.wi.gov) search “waste” to find a waste management specialist in an office near you.

Residential pharmaceutical waste

Information on the disposal of residential pharmaceutical waste and a link to lists of pharmaceutical collection sites throughout the state is available at [dnr.wi.gov](http://dnr.wi.gov) search “pharmaceutical.”
If your healthcare facility is interested in collecting household pharmaceuticals, visit dnr.wi.gov search “pharmaceutical.” Household pharmaceuticals should be clearly identified and kept segregated from wastes generated at your facility.

Disclaimer: This document is intended solely as guidance and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. Any regulatory decisions made by the Department of Natural Resources in any matter addressed by this guidance will be made by applying the governing statutes and administrative rules to the relevant facts.

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Flow Chart Evaluation Tool: Pharmaceutical Waste

This flow chart will help you determine whether a pharmaceutical waste is a hazardous waste. You will also need to determine whether the pharmaceutical waste is regulated under other rules. The flow chart notes contain important information that will help ensure correct evaluation and proper management of pharmaceutical waste. For more on what makes a waste hazardous, see “Is Your Waste Hazardous?” at https://dnr.wi.gov/files/pdf/pubs/wa/wa1152.pdf. For specific information on hazardous waste listings and characteristics, see Wisconsin hazardous waste rules at https://www.legis.state.wi.us/rsb/code/nr/nr661.pdf. Remember, you must evaluate every pharmaceutical waste in your facility!

Does the pharmaceutical have more than one active ingredient? [Yes] The pharmaceutical is not subject to evaluation by the U or P lists.

No

Is the active ingredient a P-listed waste? [Yes] The waste is a hazardous waste.

No

Is the active ingredient a U-listed waste? [Yes] The waste is a hazardous waste.

No

Is the waste ignitable? [Yes] The waste is a hazardous waste.

No

Is the waste corrosive? [Yes] The waste is a hazardous waste.

No

Is the waste reactive? [Yes] The waste is a hazardous waste.

No

Does the waste exhibit the characteristic of toxicity? [Yes] The waste is a hazardous waste.

No

The pharmaceutical is not a hazardous waste. Evaluate to determine if an infectious waste, radioactive waste or controlled substance. If not, dispose of as nonhazardous solid waste.
Flow Chart Notes

1. **The active ingredient** is the substance in the drug that is pharmaceutically active. Materials may contain more than one active ingredient. To be a P- or U-listed waste, the chemical listed as the P- or U- waste must be the sole active ingredient. Fillers, solvents, carriers, propellants, preservatives, etc. are not active ingredients.

2. Pharmaceuticals listed as a P- or U-waste solely for the characteristic of ignitability, corrosivity or reactivity that do not exhibit that characteristic at the point they become waste are not considered P- or U-listed hazardous wastes (e.g., medicinal forms of nitroglycerin). They must still be evaluated for all other hazardous waste criteria.

   Manage an unused P- or U-listed waste pharmaceutical (e.g., open medication, residual IV solution) as hazardous waste.* Manage P- or U-listed waste contaminated equipment, garments, absorbents and spill clean-up materials as hazardous waste.* Used pharmaceuticals (e.g., removed nicotine patches) are not considered P- or U-listed wastes; however, you must evaluate them for all other hazardous waste criteria. Waste residue remaining in a used syringe is considered a used pharmaceutical.

3. **Ignitable** wastes include liquids having a flash point less than 140°F, spontaneously combustible nonliquids, flammable gases and oxidizers. The waste code D001 is assigned to ignitable wastes.

   Manage a waste pharmaceutical that is ignitable as a hazardous waste.* Manage contaminated materials containing ignitable free liquids as hazardous waste.* Do not air dry contaminated materials to remove the ignitibility characteristic.

4. **Corrosive** wastes are aqueous liquids with a pH ≤ 2.0 or ≥ 12.5 or liquids that corrode plain steel at a rate > 0.250 inches per year. The waste code D002 is assigned to corrosive wastes.

   Manage pharmaceuticals meeting the definition of corrosivity as a hazardous waste.* Also manage contaminated materials with corrosive free liquids as a hazardous waste.*

5. **Reactive** wastes are normally unstable, react violently with water, detonate, explode, or, generate toxic gases when mixed with water. The waste code D003 is assigned to reactive wastes.

   Manage pharmaceuticals meeting the definition of reactivity as a hazardous waste.* Some reactive materials, such as unstable picric acid or ether, are extremely dangerous and may require detonation by a bomb squad.

6. **Toxic** wastes contain one or more contaminants that leach out of the waste under certain conditions at or above maximum allowable concentrations. Toxic wastes include certain metals (e.g., mercury), organics (e.g., cresol) and pesticides (e.g., lindane). The waste codes D004 to D043 are assigned to toxic wastes, depending on the contaminant.

   Manage waste pharmaceuticals that exhibit the toxicity characteristic as a hazardous waste.* Also manage contaminated materials exhibiting the toxicity characteristic as a hazardous waste.*

* Managing waste pharmaceuticals as hazardous waste. Hazardous waste has specific management requirements for marking, labeling, time limits for storing, type of transportation and transporter that can be used, disposal methods and record-keeping. For more information about these requirements, see [https://dnr.wi.gov/topic/Waste/Hazardous.html](https://dnr.wi.gov/topic/Waste/Hazardous.html).